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09/851,745	05/09/2001	William Rex Akers	015351-0001 (B69465)	3915

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EXAMINER	
MORGAN, ROBERT W	
ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/851,745	Applicant(s) AKERS ET AL.	
	Examiner Robert W. Morgan	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 09 October 2002 .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. In the amendment filed 10/9/02 in paper number 11, the following has occurred: Claims 23-35 has been added. Now claims 1-35 are presented for examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,924,074 to Evans in view of U.S. Patent No. 5,899,998 to McGauley et al., for the same reasons given in the previous Office Action (paper number 8). Further reasons appear below.

4. Claims 16-17 and 19 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,924,074 to Evans in view of U.S. Patent No. 6,305,377 to Portwood et al., for the same reasons given in the previous Office Action (paper number 8). Further reasons appear below.

12-30-05

(A) As per claim 35, Evans teaches the record client further comprises an image data capture device that generates image data, and the verification data includes the image data. This features is met by the data source (370, Fig. 23) that comprises physical data (374, Fig. 23) such as paper based records and photographs, and electronic mainframe data (376, Fig. 24). The converter (372, Fig. 24) receives information from the data source (370, Fig. 24) and transforms the information into an electronic format compatible with the EMR system. For example, to input physical data (374, Fig. 24) such as paper or image based data, into a patient record, the

converter (372, Fig. 24) comprises a scanner to digitize the physical data into a binary file format for incorporation into the patient's record (see: column 12, lines 35-46).

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,924,074 to Evans and U.S. Patent No. 6,305,377 to Portwood et al. in view of U.S. Patent No. 5,899,998 to McGauley et al., for the same reasons given in the previous Office Action (paper number 8). Further reasons appear below.

6. Claims 23, 28-29, 30-31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,924,074 to Evans in view of U.S. Patent No. 5,899,998 to McGauley et al.

As per claim 23, Evans teaches an electronic medical record system that includes remote servers (406, 408, 410, Fig. 24) with medical record information (see: column 12, lines 56-63). The remote servers are connected to client machines running applications such as Microsoft Windows to access (see: column 14, lines 8-16). In addition, the web servers (406, Fig. 24) allows patient data to be transfer between external source as well as updating the patient record upon a nurse or physician entry of information into the system (see: column 5, lines 29-40 and column 9, lines 27-37). This suggests that comparing and checking of medical is taking place to verify that an up-to-date medical record is available (see: column 3, lines 37-43 and column 5, lines 36-40). Evans further teaches a tiered password system to ensure patient confidentiality and provides several levels of security for access to patient data this suggests a nurse with the authorization to view the entire patient record may only update certain aspects according to the level of authorization. (see: column 15, lines 9-32).

Evans fails to teach detail encapsulation system for receiving data and preventing it from being modified.

McGauley et al. Teaches a method and system for maintaining and updating computerized medical records that use encryption to help protect and preserve the confidentiality of individual patient's medical information (see: column 6, lines 44-48).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include encryption of medical information which is a form of encapsulation as taught by McGauley et al. within the electronic medical record system as taught by Evans with the motivation of providing an efficient and cost-effective solution to transaction-oriented networking applications in outpatient medical information system, thereby securing the integrity and reliability of transmitted medical record data (see: McGauley et al. column 4, lines 65 to column 5, lines 2).

As per claim 28, Evans teaches a electronic medical record system that transfers patient data from the electronic medical records system to other healthcare providers and between external sources (see: column 3, lines 36-42 and column 4, lines 64 to column 5, lines 8).

Evans fails to explicitly teaches extracting an excerpt of the electronic medical record data from the electronic medical record data file comprises removing user readable patient identifying data.

McGauley et al. Teaches a method and system for maintaining and updating computerized medical records that use encryption to help protect and preserve the confidentiality of individual patient's medical information (see: column 6, lines 44-48). The Examiner considers

the encrypting of the patient medical information to include removing user readable patient identifying data to protect confidentiality of patient's medical information.

The obviousness of combining the teaching of McGauley et al. and Evans are discussed in the rejection of claim 23, and incorporated herein.

As per claim 29, Evans teaches an electronic medical record system that includes remote servers (406, 408, 410, Fig. 24) with medical record information (see: column 12, lines 56-63). The remote servers are connected to client machines running applications such as Microsoft Windows to access (see: column 14, lines 8-16). In addition, the web servers (406, Fig. 24) allows patient data to be transfer between external source as well as updating the patient record upon a nurse or physician entry of information into the system (see: column 5, lines 29-40 and column 9, lines 27-37). This suggests that comparing and checking of medical is taking place to verify that an up-to-date medical record is available (see: column 3, lines 37-43 and column 5, lines 36-40). Evans further teaches a tiered password system to ensure patient confidentiality and provides several levels of security for access to patient data this suggests a nurse with the authorization to view the entire patient record may only update certain aspects according to the level of authorization. (see: column 15, lines 9-32).

Evans fails to teach the encapsulating an electronic medical record file to prevent it from being modified and decrypting the encrypted encapsulated electronic medical record file at the remote location.

McGauley et al. Teaches a method and system for maintaining and updating computerized medical records that use encryption to help protect and preserve the confidentiality of individual patient's medical information (see: column 6, lines 44-48). The Examiner considers

the encrypting of the patient medical information to include a means for decrypting the medical file at a remote location in order for the information to be added to view by an authorized user.

The obviousness of combining the teaching of McGauley et al. and Evans are discussed in the rejection of claim 23, and incorporated herein.

As per claim 30, Evans teaches an electronic medical record file is an image data file. This limitation is met by the patient data structure (210, Fig. 13) that maintain a pointer to a legacy files structure (219, Fig. 13) having patient data transmitted from the legacy data system (106, Fig. 1), such as an image of a patient chart (see: column 8, lines 57-60).

As per claim 31, Evans teaches the sync file is a patient file. This feature is met by the electronic medical record system including web servers (406, Fig. 24) that allow patient data to be transfer between external sources as well as updating the patient record (see: column 3, lines 37-43 and column 5, lines 36-40). The Examiner considers the updated patient record to be the sync file, which is already compared and checked to verify the availability of an up-to-date medical record.

As per claim 33, Evans teaches transferring the sync file comprises creating a patient folder. The limitation is met by the transferring of patient between external sources (see: column 3, lines 36-42). The Examiner considers the transferring of the patient record (sync file) to be creating a patient folder one the information is received at a remote location.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,924,074 to Evans.

As per claim 24, Evans teaches an electronic medical record system where upon the creation of a patient record, the patient locator (200, Fig. 13) creates a patient data structure (210, Fig. 13) having the PID and the patient's name (see: column 8, lines 29-31). The patient data structure (210, Fig. 13) maintains a pointer to an interface files structure (211, Fig. 13) having patient data transmitted from external sources (see: column 8, lines 36-38). In addition, the patient data structure (210, Fig. 13) may maintain a pointer to a legacy files structure (219, Fig. 13) having patient data transmitted from the legacy data system (106, Fig. 1), such as an image of a patient chart (see: column 8, lines 57-60).

As per claim 27, Evans teaches a electronic medical record system that transfers patient data from the electronic medical records system to other healthcare providers and between external sources (see: column 3, lines 36-42 and column 4, lines 64 to column 5, lines 8). In addition, Evans teaches the use of progress notes (144, Fig. 4) to summarize details of the patient's condition and to review the patient's progress over time (see: column 6, lines 31-36). The Examiner considers the progress notes (144, Fig. 4) to be transferred from healthcare providers to another.

9. Claims 25-26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,924,074 to Evans.

As per claims 25-26, Evans teaches the transfer of patient data from the electronic medical records system to other healthcare providers as well as the updating of patient's record

upon a nurses or physician entry of information into the system (see: column 4, lines 64 to column 5, lines 8, column 3, lines 36-42 and column 5, lines 29-40). In addition, Evans further teaches a tiered password system to ensure patient confidentiality and provides several levels of security for access to patient data (see: column 15, lines 9-32).

Although Evans fails to teach the remote system operates in an unattended mode that allows the electronic medical data to be transferred without operator input. Evans teaches that information is updated and transferred upon input by an authorized and the Examiner considers the feature of transferring data in an unattended mode to be merely automatically updating or transferring the data without an operator inputs and an old and well-known feature in the art. Therefore, it would have been obvious to a person of ordinary skill in the art to include automatically updating or transferring data without an operator inputs within the system as taught by Evans with the motivation of providing an up-to-date medical record to authorized personnel to better treat the patient.

As per claim 32, it is rejected for the same reasons set forth in claims 25-26.

10. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,924,074 to Evans and U.S. Patent No. 6,305,377 to Portwood et al. in view U.S. Patent No. 6,370,841 to Chudy et al.

As per claim 34, Evans teaches a record server and record client coupled to the record server (see: column 14, lines 8-16).

Evans fails to teach a data reader that reads the verification data from the package.

Chudy et al. teaches automated method for dispensing bulk medication that uses scanner device (129) for transmitting scanned code to the computer (119, Fig. 25) and generating a signal

for computer (119, Fig. 25) to confirm that the package correspond to the patient's drug prescription information (see: column 14, lines 54-63).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include the scanner device for reading and transmitting prescription information as taught by Chudy et al. within the electronic medical record system as taught by Evans with the motivation of storing a broad range of prescription information and the ability to fill patient prescription in rapid and efficient manner (see: column 1, lines 31-33).

Response to Arguments

11. Applicant's arguments filed 10/9/02 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 10/9/02.

In the remarks the Applicant argues in substance that, (1) Evans in view of McGauley fails to provide a prima facie basis for the rejection of claims 1 through 15, because they fail to disclose each element of the claimed invention; and (2) Evans nor McGauley fail to disclose encapsulation, notification data and tracking the medical record.

In response to Applicant's argument that (1) Evans in view of McGauley fails to provide a prima facie basis for the rejection of claims 1 through 15, because they fail to disclose each element of the claimed invention. The Examiner respectfully submits that obviousness is determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685,686 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785,788 (Fed. Cir. 1984); and *In re Rinehart*, 531 F.2d 1048, 1052, 189

USPQ 143,147 (CCPA 1976). Using this standard, the Examiner respectfully submits that he has at least satisfied the burden of presenting a *prima facie* case of obviousness, since he has presented evidence of corresponding claim elements in the prior art and has expressly articulated the combinations and the motivations for combinations that fairly suggest Applicant's claimed invention (see paper number 8).

As such, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. However, although the Examiner agrees that the motivation or suggestion to make modifications must be articulated, it is respectfully contended that there is no requirement that the motivation to make modifications must be expressly articulated within the references themselves. References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969).

The Examiner is concerned that Applicant apparently ignores the mandate of the numerous court decisions supporting the position given above. The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i) obviousness does not require absolute predictability;
(ii) non-preferred embodiments of prior art must also be considered; and
(iii) the question is not express teaching of references, but what they would suggest.

In particular, Applicant clearly fails to properly consider using encryption to maintain and update computerized medical records of McGauley et al. within the system taught by Evans. It is respectfully submitted that Applicant's position is clearly improper based on the aforementioned case law.

Further, according to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory limitation as to the number of references that may be used to demonstrate obviousness...not what references expressly state but what they would reasonably suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

As such, it is respectfully submitted that an explanation based on logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner both in the present Office Action as well as the prior Office Action, *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter., 4/22/93).

As such, it is respectfully submitted that Applicant appears to view the applied references, separately and in a vacuum, without considering the knowledge of average skill in the art, and further fails to appreciate the breadth of the claim language that is presently recited.

Moreover, the issue at hand is not whether the applied references specifically teaches each and every feature recited by Applicant, *per se*, but rather, whether or not the prior art, when taken in combination with the knowledge of average skill in the art, would put the artisan in possession of the features as claimed. With regard to this issue, the courts have held that even if

a patent does not specifically disclose a particular element, said element being within the knowledge of a skilled artisan, the patent taken in combination with that knowledge, would put the artisan in possession of the claimed invention. *In re Graves*, 36 USPQ 2d 1697 (Fed. Cir. 1995).

In response to Applicant's argument that (2) Evans nor McGauley fail to disclose encapsulation, notification data and tracking the medical record. The Examiner respectfully submits that the McGauley reference, and not Evans, *per se*, that was relied upon for the specific teaching of maintaining and updating computerized medical records that use encryption (see: column 6, lines 44-48). Evans was relied on for primarily teaching of the healthcare provider acknowledging that a patient record has been reviewed (see: column 2, lines 45-58). In addition, Evans further teaches tracking and description of patient data within the system (see: column 9, lines 27-37). Thus, the proper combination of the applied references would be the incorporation of McGauley encryption of medical records within electronic medical record system of Evans.

In addition, the Examiner respectfully submits the McGauley reference describes encryption of medical record for the purpose of preventing and preserving the confidentiality of individual patient's medical information. This is a clear indication that the medical record information is encapsulated by encryption cannot be modified.

In sum, it is respectfully submitted that the rejection given in the prior Office Action is indeed proper and should be maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (703) 605-4441. The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7687 for regular communications and (703) 305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

RWM
rwm
December 30, 2002

DINH X. NGUYEN
PRIMARY EXAMINER